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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,368	07/29/2003	Luiz Belardinelli	02-479-C	6263

7590 04/09/2007

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,368	BELARDINELLI, LUIZ	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 29, 2006 (amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-15, 17-18 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12.21.2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims **5, 16 and 19-20** have been cancelled, claims **1, 6-9. 13, 17 and 25-26** have been amended, the disclosure's abstract has been amended, and no new claims have been added as per the amendment filed August 29, 2006. One additional Information Disclosure Statement (1 IDS) filed December 21, 2006 has been received with all cited references and made of record.

Claims **1-4, 6-15, 17-18 and 21-30** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993). .

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-11*** of copending Application No. **11/253,322** (now cited as a PG PUBS document; see PTO-1449 ref. **B6**). Although the conflicting claims are not identical, they are not patentably

distinct from each other because the method of imaging and the alleged active ingredient (CVT-3164) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Applicant has noted the presence of this rejection but has not otherwise responded. Therefore this rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***21-61*** of copending Application No. **10/766,403** (now cited as a PG PUBS document; see PTO-1449 ref. **A6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Applicant has noted the presence of this rejection but has not otherwise responded. Therefore this rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***11, 14-27, 29-30, 34 and 36-37*** of copending Application No. **11/070,768** (now cited as a PG PUBS document; see PTO-1449 ref. **E6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Applicant has noted the presence of this rejection but has not otherwise responded. Therefore this rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4***of U. S. Patent No. **7,109,180** (PTO-1449 (#6) ref. **K6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033. Therefore the two applications are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***5-8 and 10-22*** of U. S. Patent **7,183,264** (See PG Pubs ref. US 2004/0038928; PTO-1449 (#6) ref. **D6**; see also PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***10-24*** of U. S. Patent No. **7,144,872** (PTO-1449 (#6) ref. **AA6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***9, 10 and 16*** of U. S. Patent No. **6,641,210** (PTO-1449 (#6) ref. **H6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4*** of U. S. Patent No. **6,770,634** (PTO-1449 (#6) ref. **I6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033. Therefore the two claim sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **11, 14-27, 29-30, 34 and 36-37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***29-31*** of U. S. Patent No. **6,214,807** (PTO-1449 (#2) ref. **AL2**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredients, CVT-3033 or CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **11, 14-17, 24-27, 29-30, 34 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims *11-13* of U. S. Patent No. **6,403,567** (PTO-1449 (#1) ref. **AB1**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims *2-4* of U. S. Application No. **11/588,834** (PTO-1449 (#6) ref. **G6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033 . Therefore the two applications are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***29-31*** of U. S. Application No. **11/522,120** (PTO-1449 (#6) ref. **F6**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3146. Therefore the two applications are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-4, 6-15, 17-18 and 21-30** have been considered but are deemed to be moot in view of the new grounds of rejection. Applicant's newly cited prior art necessitated this new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under 35 U.S.C. §102(**e**) as being anticipated by **Zablocki et al. '567** (PTO-1449 ref. **A13**).

Applicant is referred to claims ***1, 8, 10 and 11-13*** wherein the compound, also known as CVT-3164, is disclosed as part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.

See also **CV Therapeutics '779** (PTO-1449 ref. **B2**) which is the PCT equivalent to the **'567** reference and also anticipates the instant noted claims for the same reasons.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Examiner notes that in the instant independent claims CVT-3146 is one member of a Markush group and therefore all of the claims are deemed to be properly rejected herein.

Applicant argues that the instant claims have not been anticipated because the blood flow limitation of instant claim **1** is not found in the cited **'567** patent claims or patent disclosure. Examiner respectfully disagrees because the particular rate of blood flow permitted by the administration of the same active ingredient to a host in need thereof is a variable within the control of the ordinary practitioner seeking to optimize the subject matter of either the instant claimed method or the method claimed in the **'567** reference. Therefore the manipulation of this variable is inherently included within the scope of both instant claim **1** and claim *11* of the **'567** patent.

Applicant is specifically referred to claim *11* wherein the term "... administering to a mammal a therapeutically effective amount of a compound of claim *1* that is sufficient to stress the heart and induce a coronary steal situation for the purposes of imaging the heart," a disclosure that appears to be equivalent to the term "producing coronary vasodilation with little peripheral vasodilation" found in instant claim 1. Examiner assumes that "coronary vasodilation" (increase in the diameter of the CVT-3164-treated blood vessels) will permit a more rapid flow of blood through the heart and that administration of CVT-3164 will permit this to happen to an extend proportional to the amount of this active ingredient administered to the host. Examiner also notes in Taber's Cyclopedic Medical Dictionary (19th Ed., page 2048) that the term "steal" is defined as "deviation of blood flow from its normal

course or rate of flow," a phenomenon that will happen when CVT-3164 is administered regardless of whether reference is made to the claim **1** language of the instant application or the language of the **'567** patent's claim *11*. Therefore, while the particular language and limitations of instant claim **1** and patented claim *11* differ superficially, examiner finds the underlying subject matters encompassed by these two claims to be overlapping if not identical, and therefore that anticipation of claim **1** by patented claim *11* remains an appropriate conclusion.

For these reasons the instant rejection has been maintained.

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under 35 U.S.C. §102(**a**) and/or (**b**) as being anticipated by **Gao et al.** (PTO-1449 ref. **C2**).

Applicant is referred to the reference at its abstract wherein both CVT-3033 and CVT-3164 are disclosed as having the desirable properties of inducing short-term coronary vasodilation during myocardial imaging in the presence of radionuclides. The copy of the reference indicates a publication date of July , 2001, which without more complete date information is deemed to be sufficient to render the instant claimed subject matter anticipated.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Applicant argues that the lack of identical language means that **Gao et al.** does not anticipate the instant claims. Examiner respectfully disagrees. Applicant is referred to **Gao et al.** at page 215 at column 1, beginning in the "Discussion" section: in particular the second sentence of the first paragraph of this section refers specifically to CVT-3164 and that both this compound and a related compound (CVT-3033) induced "coronary vasodilation" but that "the duration of their effect was remarkably shorter." This disclosure anticipates instant claim **1** wherein "coronary vasodilation" is asserted as the primary effect of CVT-3164. The associated effects indicated by the terms "with little peripheral vasodilation" and "increase the average coronary peak flow velocity to at least about 16.5 cm/sec" are deemed to be inherently a consequence of "coronary vasodilation." "Coronary vasodilation" is a phenomenon induced by administration of CVT-3164 and is a variable controllable by routine variation of dosage, a variable clearly within the purview of the ordinary practitioner seeking to optimize the prior art via routine experimentation. Therefore, the details of the noted effects not presenting, or

presenting, respectively, are deemed to be limitations that do not permit applicant to avoid the finding of anticipation.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-4, 6-15, 17-18 and 21-30** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Zablocki et al. '567** (PTO-1449 ref. **AB1**).

The instant claims are directed to methods of selective cardiac vasodilation for the purpose of enhancing the imaging of cardiac circulation by administration of an A_{2A} receptor agonist including the compounds CVT-3164 and CVT-3033.

Zablocki et al. '567 (PTO-1449 ref. **AB1**) discloses in claims ***1, 8, 10 and 11-13*** and in associated textual explanations that the compound, also known as CVT-3164, is part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.

Zablocki et al. '567 does not expressly disclose all of the specific details of the administration of pharmaceutical compositions containing CVT-3164 found in the instant claims.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to conduct routine experimentation to determine the optimal conditions of administration of a CVT-3164-containing compositions to produce the best possible radionuclide-based cardiac circulatory imaging.

Therefore, the instant claimed method of inducing selective myocardial vasodilation for the purpose of enhancing the imaging of cardiac circulation would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 29, 2006 have been fully considered but they are not persuasive.

Examiner notes that in the instant independent claims CVT-3146 is one member of a Markush group and therefore all of the claims are deemed to be properly rejected herein.

Applicant's arguments are noted and have already been addressed in the responses to the anticipation rejections citing the **'567** patent and the **Zao et al.** references supra. These responses to applicant's arguments are incorporated herein by reference in their entirety.

The instant Office action has not been made final because of new grounds of rejection herein that could have been made in the first Office action but were not.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

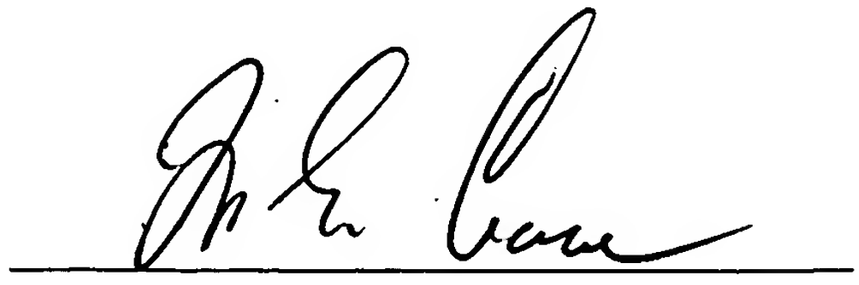
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to

the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
03/29/2007



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